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10/637,149	08/08/2003	Gerald E. McDonnell	STRSP0119US	3426

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/637,149	MCDONNELL ET AL.	
	Examiner	Art Unit	
	MICHELLE S. HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 31-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 31-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 3/24/2011.

Claims 1 and 31-75 are under current examination.

Any rejection(s) and/or objection(s) not reiterated herein have been withdrawn.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/24/2011 has been entered.

Response to Amendment

The declaration under 37 CFR 1.132 filed 3/24/2011 is insufficient to overcome the rejection of claims 1 and 31-75 based upon 35 USC 103 as set forth in the last Office action because:

While the declaration does show that IFDOs have similar inactivation susceptibility to prion for *some* inactivation means, the prior art (Burdon, 1989) demonstrates that not every inactivation means is the same for IFDO and prions. For example, the teachings of Burdon indicate that the two types of agents differ in their reaction to inactivating agents targeting nucleic acids and lipid membranes.

The declaration provides inactivation methods for either the prion or IFDO protein, wherein the treatment condition is one of the following: NaOH, steam

sterilization, alkaline formulation, hydrogen peroxide (gas or liquid) and Environ LpH. The teachings by Ernst and Race disclose a method of inactivating a prion using LpH, comprising various phenol compounds. It is noted that the claims are drawn to a method of treating a body contaminated with infectious prions using a genus of endless combinations of different ingredients, including phenols of different types, sulfonates of different types, surfactants of different types, etc. However, the scope of the declaration (the provided data) is not commensurate with the scope of the claims and it is not clear that the inactivation properties of a prion are comparable to that of an IFDO using the claimed methods from the declaration or the cited prior art.

Separately, it is noted that the IFDO assay is an *in vitro* assay; see p. 4 of the declaration which states that the assay is carried out as described in the specification and p. 14 of the specification notes that the IFDOs are artificially cultured in broth and cultured. It is interesting to note that the *in vitro* results of LpH treatment (p. 3 of the declaration) provide differential results in that this treatment is ineffective in the inactivation of a prion but effective in IFDO assays at a specific and single set of conditions (5%, 20 degrees C, 30 min). It is not clear how such a finding would support that IFDO is a valid surrogate for prions, and that sterilization compositions and/or conditions that are effective against IFDO are "equally effective" against prions as alleged on p. 2 of the declaration. Also see discussion below of teachings by Burdon which provide the differential properties of a prion and an IFDO.

For at least the reasons above, this declaration is insufficient to overcome the pending rejection. It is noted here that the written description rejection has been withdrawn for showing some similar results in inactivating prions and IFDOs.

Claim Rejections - 35 USC § 103-MAINTAINED

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 31-40, 45-52, and 55-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of US Patent No. 6720355 (hereinafter as "Prusiner") and Ernst and Race (*J Virological Methods*, 1993). The claims are drawn to (in part): a method of treating a body which is contaminated with infectious prions, the method comprising contacting a body with a composition comprising one or more phenols and an organic sulfonate, the one or more phenols

comprising: o-benzyl-p-chlorophenol; o-phenylphenol; or a mixture of two or more thereof; see claim 1.

Prusiner describes a method of using compositions for inactivating infectious prions on infected surfaces, such as medical equipment, food products, blood (col. 1, lines 35+, col. 4, line 30 and instant claims 1, 31-33, 36, 57-59 and 62, in part). The compositions comprise an organic sulfonate, including an alkyl sulfonate (sodium salt) and an alkyl sulfate which was shown to effectively denature prions (see col. 54-55, Ex. 19 and instant claims 1, 40 and 55, in part). Note that the instant specification describes the use of an anionic surfactant which may include an alkyl sulfonate; see para. 47. Thus, Prusiner meets the claim limitations of a composition comprising a surfactant (instant claim 56, in part), an alkylaryl anionic surfactant (instant claims 67 and 68, in part) and wherein the surfactant comprises a sulfonic acid (instant claim 69, in part) and wherein the surfactant comprises an alkyl sulfonate (instant claim 70, line 3, in part). The author also discloses using compositions which are either acidic or basic (alkaline); see col. 3, lines 39+ disclosing a pH of 4.0 or less and a pH of 10 or more and instant claims 46 and 47. A solvent ingredient includes water in varying amounts (col. 12, lines 51+, col. 13-17 and instant claim 48). Inorganic salts in the composition are found in col. 6, lines 60+; see instant claims 52 and 74.

Prusiner does not disclose a method using phenols (including o-benzyl-p-chlorophenol and o-phenylphenol of claims 1, 39 and 56) or a composition further comprising one or more cosolvents (see claims 51 and 73).

Prusiner does not disclose a method wherein at least one phenol has a Log Pc value of at least about 2.5 (claim 45), a method of using a composition wherein the composition is in the form of a concentration which is diluted with water (claims 49 and 71) and a method wherein the concentrate has a total phenol concentration from about 0.1M to about 1.0M (claims 50 and 72).

Prusiner does not disclose a method of treating a body wherein the body comprises a work surface in a hospital or research facility (claims 34 and 60), medical waste (claims 35 and 61), cages used for housing animals (claims 36 and 63) and wherein the method is used to decontamination a disinfection of sterilization system (claims 38 and 64).

Ernst and Race describe methods of inactivating the scrapie agent using different concentrations of LpH, an aqueous and phenolic disinfectant (see abstract and p. 196). This composition comprises o-benzyl-p-chlorophenol, #2-phenylphenol (also called o-phenylphenol), p-tertiary amylphenol, and hexylene glycol (see p. 196 and instant claims 1, 39, 56, 65 and 66). The authors describe using different concentrations of LpH which were made by serial dilutions (p. 196, para. 1). Note that the instant specification describes a cosolvent in para. 45 and such a cosolvent may include hexylene glycol which is found in the LpH composition; thus, claims 51 and 73 drawn to a cosolvent are met by this reference.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Prusiner and Ernst and Race to perform a method of inactivating infectious prions. One would have been motivated to do so in order to make a composition

comprising ingredients known to inactivate infectious prions, including alkyl sulfonates, o-benzyl-p-chlorophenol, #2-phenylphenol (also called o-phenylphenol) and hexylene glycol, a cosolvent. There would have been a reasonable expectation of success given the ingredients have been characterized in view of inactivating infectious prions, as shown by the cited art. Also, see MPEP 2144.06 for the following:

I. < COMBINING EQUIVALENTS KNOWN FOR THE SAME PURPOSE
"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Prusiner and Ernst and Race to perform a method of inactivating infectious prions at different concentrations of ingredients in a composition, including at least one phenol having a Log Pc value of at least about 2.5, and further diluting a more concentrated solution with water so that the total phenol concentration is between 0.1M and 1.0M. One would have been motivated to do so for the gain of optimizing results, with the result effective parameter being inactivation of infectious prions at a controlled rate. Note that Prusiner describes using water as a solvent ingredient as discussed above. There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly use as shown by the applied

prior art (e.g. serial dilution of a composition taught by Ernst and Race, as discussed above).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Prusiner and Ernst and Race to perform a method of inactivating infectious prions comprising using the compositions on surfaces or in places wherein infectious prions may be transmitted, including surfaces of a hospital or research facility, medical waste, animal cages, or sterilization systems. One would have been motivated to do so in order to ensure safety against prion transmission or for preventative maintenance. There would have been a reasonable expectation of success given the compositions described by the cited prior art were demonstrated to be effective in inactivating infectious prions.

The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 54 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6720355 (hereinafter as "Prusiner") and Ernst and Race (*J Virological Methods*, 1993-previously cite) as applied to claims 1, 31-40, 45-52, and 55-74 above, and further in view of US Patent No 7252720 (hereinafter as "Foster"-previously cited).

The claims are further drawn to a method of using a composition further comprising brine.

The combined teachings of Prusiner and Ernst and Race disclose a method of treating a body (e.g. surface) which is contaminated with infectious prions, the method

comprising contacting the body with a composition comprising one or more phenols and an organic sulfonate, the one or more phenols comprising: o-benzyl-p-chlorophenol; o-phenylphenol; or a mixture of two or more thereof; e.g., see claim 1.

The combined teachings of Prusiner and Ernst and Race do not disclose using a composition comprising brine in the method of inactivated prions. Although Prusiner discloses the use of salts, Prusiner does not disclose using water heavily saturated with salt.

Foster describes the removal of prion infectivity (see whole document). The authors provide that the use of concentrated solutions of salts, such as 2M sodium chloride, is effective in both eluting and completely removing adsorbed prion infectivity (abstract and col. 2, lines 62+). The authors further describe a method of cleaning a reusable substrate via washing the substrate with a salt solution of a concentration of at least 1.0 M (see col. 2, lines 62+-col. 3).

It would have been obvious to one of ordinary skill in the art to incorporate the use of brine in the method taught by Prusiner and Ernst and Race. One would have been motivated to do so because Foster teaches that a high concentration of salt, including sodium chloride, in solution is effective in cleaning a substrate (e.g. medical surfaces). There would have been a reasonable expectation of success given the ingredients, including a high salt solution and phenols, have been characterized in view of prion removal and inactivation. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6720355 (hereinafter as "Prusiner") and Ernst and Race (*J Virological Methods*, 1993-previously cited) as applied to claims 1, 31-40, 45-52, and 55-74 above, and further in view of US Patent No 7001873 (hereinafter as "McDonnell") and/or US Patent No 5326789 (hereinafter as "Narayanan").

The claims are further drawn to a method of using a composition using water, glycolic acid, dodecyl benzene sulfonic acid and hexylene glycol (see claim 53).

The combined teachings of Prusiner and Ernst and Race disclose a method of treating a body (e.g. surface) which is contaminated with infectious prions, the method comprising contacting the body with a composition comprising one or more phenols and an organic sulfonate, the one or more phenols comprising: o-benzyl-p-chlorophenol; o-phenylphenol; or a mixture of two or more thereof; e.g., see claim 1.

Note that Ernst and Race teach the LpH composition which comprises glycolic acid and hexylene glycol in addition to o-benzyl-p-chlorophenol and o-phenylphenol (p. 196).

Also, note that Prusiner teaches using water as a solvent ingredient as discussed above and SDS or sodium dodecyl sulfate (see title). The authors also teach the use of an alkyl benzene sulfonate (col. 7, line 45).

Prusiner and Ernst and Race do not specifically disclose the use of dodecyl benzene sulfonic acid.

McDonnell teaches using a solution comprising surfactants for the attacking and removing prions from a surface (see abstract). The author teaches the use of the surfactant, dodecyl benzene sulfonic acid (col. 3, lines 12).

Naranayan teaches compositions comprising an anionic surfactant, including SDS or a dodecylbenzene sulfonate (see abstract).

It would have been obvious to one of ordinary skill in the art to further include an anionic surfactant, including a dodecylbenzene sulfonate, in the composition used the method taught by Prusiner and Race and Ernst. One would have been motivated to use this known surfactant as an equivalent to SDS which is comprised in the composition taught by Prusiner. Further, McDonnell teaches its use in a composition for attacking and removing prions from a surface. There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly used (e.g. making a composition requiring a known surfactant) as shown by the prior art. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 3/24/2011 have been fully considered but they are not persuasive. Applicant points to the submitted declaration

However, the declaration has been found to be insufficient for the reasons as set forth above.

Applicant contends that the examples show that an unexpected synergy is exhibited by the claimed combination.

In response, it is noted that it is unclear where in the specification is there support for the alleged synergy. Applicant is invited to point to such support. Separately, it is not clear what the unexpected synergy that Applicant refers to in the examples is. The examples are drawn to the inactivation of an IFDO whereas, in contrast, the claims are directed to a method of inactivating a prion. Also, see above in view of why the declaration is insufficient.

Applicant argues that Applicant found that the solubility of the phenol in the composition has an effect on the degree to which the protein is complexed and that, the lower the solubility of the phenol in the formulation, the greater the degree of complexation, i.e., the more effective the phenol formulation is at prion inactivation; see p. 4 of Remarks. Applicant points to Example 3 which shows log IFDO reduction.

In response, as noted above, the claims are directed to a method of inactivating a prion whereas the example is drawn to the inactivation of a separate molecule, described by the prior art to possess differential structural and functional properties. Applicant has provided no support that such properties of a prion are correlated to that of an IFDO.

Applicant further argues that there is simply no evidence that it would have been obvious to combine the teachings of Prusiner and Ernst and Race to include a phenol with a Log Pc value of at least about 2.5. Applicant argues that a person of ordinary skill would expect agents having a greater hydrophillic nature, to have been more effective and one of ordinary skill would not use a phenol with a Log Pc value of at least about 2.5.

As noted above, MPEP 2144.06 provides the following which supports combining the teaching of Prusiner and Ernst and Race:

I. < COMBINING EQUIVALENTS KNOWN FOR THE SAME PURPOSE
"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

In view of the limitation, a phenol with a Log Pc value of at least about 2.5, it would have been obvious to use different phenols at different concentrations for one of ordinary skill in the art for the gain of optimizing results. It is noted here that p. 8 of the instant specification provides support that the hydrophobicity of a phenol is an inherent feature of the compound.

For the reasons set forth above, the arguments are not found to be persuasive and the rejections are maintained.

Double Patenting-NEW

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 31-38, 46-64 and 71-75 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 9-16 of copending Application No. 12/711446 (PGPUB 20100248287). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method of inactivating prions comprising the same steps and the some compositions comprising phenols and salts.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE S. HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ZACHARIAH LUCAS can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. S. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Supervisory Patent Examiner, Art Unit 1648